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COVeRs to impRove AesthetiC ouTcome after Surgery for Chronic subdural haemAtoma by buRr hole trepanation (CORRECT-SCAR): protocol of a Swiss single-blinded, randomised controlled trial

Stienen, Martin N ; Akeret, Kevin ; Vasella, Flavio ; Velz, Julia ; Jehli, Elisabeth ; Scheffler, Pierre ;
Voglis, Stefanos ; Bichsel, Oliver ; Smoll, Nicolas Roydon ; Bozinov, Oliver ; Regli, Luca ; Germans,
Menno R

Abstract: INTRODUCTION: Outcomes rated on impairment scales are satisfactory after burr hole trepanation for chronic subdural haematoma (cSDH). However, the surgery leads to bony defects in the skull with skin depressions above that are frequently considered aesthetically unsatisfactory by the patients. Those defects could be covered by the approved medical devices (burr hole covers), but this is rarely done today. We wish to assess, whether the application of burr hole covers after trepanation for the evacuation of cSDH leads to higher patient satisfaction with the aesthetical result at 90 days postoperative, without worsening disability outcomes or increasing the complication rate. METHODS AND ANALYSIS: This is a prospective, single-blinded, randomised, controlled, investigator-initiated clinical trial enrolling 80 adult patients with first-time unilateral or bilateral cSDH in Switzerland. The primary outcome is the difference in satisfaction with the aesthetic result of the scar, comparing patients allocated to the intervention (burr hole cover) and control (no burr hole cover) group, measured on the Aesthetic Numeric Analogue scale at 90 days postoperative. Secondary outcomes include differences in the rates of skin depression, complications, as well as neurological, disability and health-related quality of life outcomes until 12 months postoperative. ETHICS AND DISSEMINATION: The institutional review board (Kantonale Ethikkommission Zürich) approved this study on 29 January 2019 under case number BASEC 2018-01180. This study determines, whether a relatively minor modification of a standard surgical procedure can improve patient satisfaction, without worsening functional outcomes or increasing the complication rate. The outcome corresponds to the value-based medicine approach of modern patient-centred medicine. Results will be published in peer-reviewed journals and electronic patient data will be safely stored for 15 years.

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BMJ Open COVeRs to impRove AesthetiC ouTcome after Surgery for Chronic subdural haemAtoma by buRr hole trepanation (CORRECT-SCAR): protocol of a Swiss single-blinded, randomised controlled trial

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ABSTRACT

Introduction Outcomes rated on impairment scales are satisfactory after burr hole trepanation for chronic subdural haematoma (cSDH). However, the surgery leads to bony defects in the skull with skin depressions above that are frequently considered aesthetically unsatisfactory by the patients. Those defects could be covered by the approved medical devices (burr hole covers), but this is rarely done today. We wish to assess, whether the application of burr hole covers after trepanation for the evacuation of cSDH leads to higher patient satisfaction with the aesthetical result at 90 days postoperative, without worsening disability outcomes or increasing the complication rate.

Methods and analysis This is a prospective, single-blinded, randomised, controlled, investigator-initiated clinical trial enrolling 80 adult patients with first-time unilateral or bilateral cSDH in Switzerland. The primary outcome is the difference in satisfaction with the aesthetic result of the scar, comparing patients allocated to the intervention (burr hole cover) and control (no burr hole cover) group, measured on the Aesthetic Numeric Analogue scale at 90 days postoperative. Secondary outcomes include differences in the rates of skin depression, complications, as well as neurological, disability and health-related quality of life outcomes until 12 months postoperative.

Ethics and dissemination The institutional review board (Kantonale Ethikkommission Zürich) approved this study on 29 January 2019 under case number BASEC 2018–01180. This study determines, whether a relatively minor modification of a standard surgical procedure can improve patient satisfaction, without worsening functional outcomes or increasing the complication rate. The outcome corresponds to the value-based medicine approach of modern patient-centred medicine. Results will be published in peer-reviewed journals and electronic patient data will be safely stored for 15 years.

Trial registration number NCT03755349.

Strengths and limitations of this study

- The study might prove that surgeons can positively influence the satisfaction of their patients by a minor and inexpensive technical nuance (adding a burr hole cover before skin closure).
- By randomising patients with unilateral chronic subdural haematoma (cSDH) into an intervention and control group, the effect of potential confounders should be minimised.
- The inclusion of patients with bilateral cSDH allows studying a completely unbiased effect of burr hole covers on the outcome of interest (as each patient serves as his/her own internal control).
- The 90-day period of the primary endpoint may be too short to detect a difference in outcome (as skin depressions progressively occur over time), but additional 12-month outcome assessment should capture this.

INTRODUCTION

Outcome in terms of recovery of impaired neurological function is generally satisfactory after burr hole trepanation for the evacuation of chronic subdural haematoma (cSDH).^{1 2} Despite being considered a relative minimally invasive type of surgery, it requires drilling holes in the patient's skull. With progressive haematoma reabsorption during the follow-up, patients may develop skin depressions above the burr hole sites ([figure 1](#)).^{3 4} Theoretically, burr holes could be covered by approved medical devices (burr hole covers) after cSDH evacuation and prior to closing the wound.



Figure 1 Example of skin depression above the burr holes in a male patient in his late 80s, about 2 years following frontal and parietal burr hole trepanation for the evacuation of a large chronic subdural haematoma. The photo was taken with his permission and at this time. He continued to lead an active life. On inquiry, he and his wife confirmed feeling troubled by the well-visible and stigmatising skin depressions.

This has not become standard of care, however, and we previously set out to explore the prevalence and relevance of skin depressions, as well as today's pattern of care by conducting a cross-sectional survey-based study among neurosurgeons globally. Analysing 576 responses from 78 different countries, 76% of neurosurgeons stated that their patients complained about skin depressions after burr hole trepanations more or less frequently.⁵ In contrary, only 28% of neurosurgeons currently apply burr hole covers more or less frequently for this indication. Their reluctance was mostly explained by a lack of evidence for any proven benefit, less so for the fear of an increased complication rate, technical difficulties and financial reasons. Around three-quarters (78% of neurosurgeons) indicated that they would consider applying burr hole covers for this indication, in case a high-quality trial demonstrated its efficacy and safety.⁵

We retrospectively reviewed a series of $n=28$ cSDH patients (64 burr holes) treated at our department, of which $n=11$ patients had received a burr hole cover on 14 burr holes at the surgeon's discretion. Applying the Aesthetic Numeric Analogue (ANA) scale to rate the aesthetical result of the surgery,⁶ patients rated sites where the burr hole was covered more favourably than sites where the burr hole was left uncovered (ANA 9.3 ± 0.74 vs 7.9 ± 1.0 ; $p < 0.001$).⁴ In addition, the rates of skin depression were as low as 7% in the intervention group and as high as 92% in the control group ($p < 0.001$). Evidently, the prior results were subject to selection bias, patients were not blinded for the intervention and the study was underpowered to estimate possible group differences in complications.⁴ These preliminary findings were a promising starting point for further and more in-depth

research, because filling this knowledge gap is likely to affect future management of cSDH patients.

METHODS AND ANALYSIS

Study goals and objectives

The COVeRs to impRove aesthetiC ouTcome after Surgery for Chronic subdural haemAtoma by buRr hole trepanation trial aims to demonstrate that the placement of burr hole covers on the burr hole sites improves patient satisfaction with the aesthetic outcome of the surgical procedure at 3 and 12 months postoperative. It also aims to demonstrate that clinical outcomes (disability, neurological function and health-related quality of life (hrQoL)) remain similar and complication rates (eg, surgical site infections (SSIs), cSDH recurrences, etc) are not increased by applying burr hole covers.

The primary objective is to compare mean ANA scores (patient satisfaction with the aesthetic result of the surgery) between the intervention and control group at 90 days postoperatively. Secondary/safety objectives are to compare mean ANA scores, rates of skin depression, impairment in activities of daily living (ADLs), disability (modified Rankin scale (mRS)), hrQoL (Euro-QoL five dimension (EQ)-5D), neurological status (National Institute of Health Stroke scale (NIHSS)), complications and residual haematoma volume between the intervention and control group at 3 and 12 months postoperative.

Study design

Prospective, single-blinded, randomised, controlled, investigator-initiated clinical trial. The trial is conducted at the University Hospital Zurich, Switzerland. The study will be reported according to the Consolidated Standards of Reporting Trials guidelines.⁷

Eligibility criteria

Participants fulfilling all of the following inclusion criteria are eligible for the study:

- ▶ Patients with first-time cSDH (hypodense, isodense, hyperdense or mixed type in CT imaging), scheduled for unilateral or bilateral double burr hole trepanation under general anaesthesia.
- ▶ Patient age ≥ 18 years.
- ▶ Patient non-comatose at time of inclusion (Glasgow Coma Scale (GCS) > 8 points).
- ▶ Patient able to communicate (in terms of ability to hear, see, speak and understand).

The presence of any one of the following exclusion criteria will lead to exclusion of the participant:

- ▶ Patient with recurrent cSDH or previous surgery for cSDH.
- ▶ Patient with cSDH treated by craniotomy or by single burr hole trepanation.
- ▶ Patient with cSDH treated in local anaesthesia.
- ▶ Patient unlikely to attend the follow-up (due to reasons of residency, dismal prognosis, etc).
- ▶ Pregnancy.

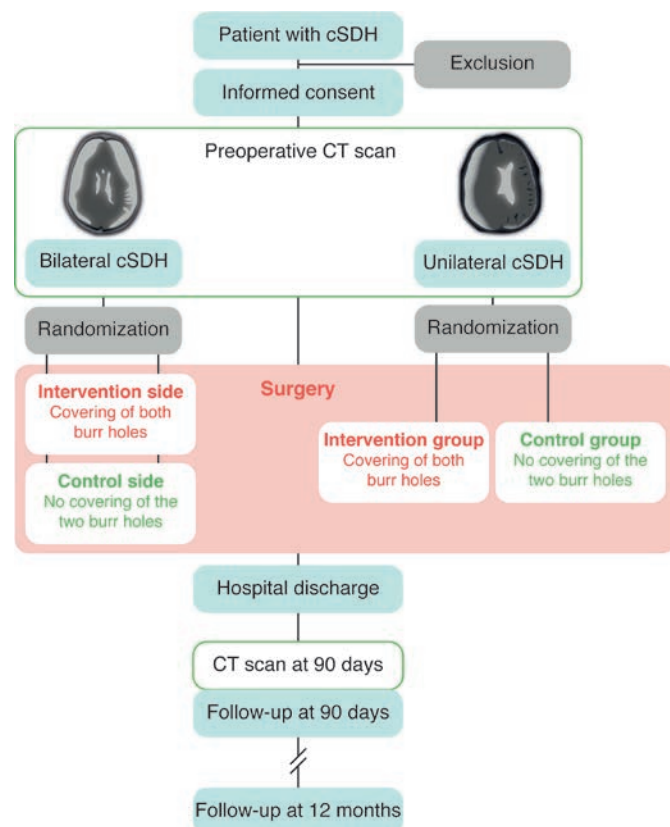


Figure 2 Illustration of the algorithm of the CORRECT-SCAR trial. cSDH, chronic subdural haematoma; CORRECT-SCAR, COVeRs to impRove aesthetiC ouTcome after Surgery for Chronic subdural haemAtoma by buRr hole trepanation.

- ▶ Known allergy against or incompatibility with titanium.
- ▶ Known or suspected non-compliance.
- ▶ Inability to follow the study procedures, for example, due to psychological disorders, dementia of the participant.

Intervention and study groups

A study algorithm can be found in [figure 2](#) and [table 1](#) outlines all visits and procedures.

1. Patients with unilateral cSDH

All patients randomised into the control group will be treated according to our standard protocol for cSDH evacuation (online supplementary digital content 1). All patients randomised into the intervention group will be treated according to our standard protocol for cSDH evacuation with one exception: placement of a burr hole cover (UN3 BURR HOLE COVER, 20 mm, W/TAB, Item code 53–34520, Stryker, Kalamazoo, Michigan, USA) that is fixed with two screws (UNIII AXS SCREWS, SELF-DRILLING, 1.5×4 MM, Item code 56–15934, Stryker) on both burr holes after evacuation of the haematoma and prior to skin closure.

2. Patients with bilateral cSDH

Patients with bilateral cSDH serve as their own internal control. They are randomised concerning the intervention or control side, being either the side with larger or smaller haematoma, respectively.

All patients are blinded concerning the study group/side allocation. For application of the burr hole cover, surgeons will be instructed to firmly press the burr hole cover on the burr hole before receiving the screws from the scrub nurse in order to prevent from screws accidentally falling into the subdural space. For this purpose, a standard operating procedure (SOP) has been developed (online supplementary digital content 2). No dexamethasone is applied to surgical candidates who are enrolled into this trial.

Primary outcome and follow-up

For the primary outcome, patient satisfaction with the aesthetic results of the scar is determined using a patient-rated outcome measure, the ANA scale,⁶ ranging from 0 (dissatisfied) to 10 (very satisfied), at 90 days postoperative. The outcome is assessed by mailed questionnaire and collected by a study coordinator.

Secondary outcomes

- ▶ Patient satisfaction with the aesthetic result of the scar, determined by the ANA scale, at 12 months postoperatively (mailed questionnaire, collected by a study coordinator).
- ▶ Impairment in ADLs (eg, when hairdressing, combing, washing, etc), rated as ‘yes’ versus ‘no’, at 90 days and 12 months postoperative (mailed questionnaire, collected by a study coordinator).
- ▶ Rate of skin depression, rated as ‘yes’ versus ‘no’, at 90 days and 12 months postoperative (mailed questionnaire, collected by a study coordinator).
- ▶ Disability, determined by the mRS (ranging from 0 (no disability) to 6 (dead)) at 90 days.
- ▶ HrQoL, determined by the EQ-5D (allowing the calculation of both the EQ-5D index that ranges from 0.074 (worst hrQoL) to 1.00 (best hrQoL) using European norms and the EQ-5D Visual Analogue Scale (VAS) (ranging from 0 (worst hrQoL) to 100 mm (best hrQoL)), at 90 days and 12 months postoperative (mailed questionnaire, collected by a study coordinator).
- ▶ Neurological outcome, determined by the NIHSS (ranging from 0 (no neurological deficit) to 42 (severe neurological deficit)), at 90 days.
- ▶ Home time, as surrogate marker of disability,⁸ at 90 days and 12 months.

Further safety outcomes

- ▶ Intraoperative and postoperative complications up to 90 days and 12 months, in particular cSDH recurrence and SSIs.
- ▶ Residual cSDH volume in ccm,³ absolute (ccm³) and relative (per cent) cSDH clearance at 90 days postoperative (measured by two neuroradiologists independently, otherwise not involved in the project, using volumetric analysis).

Table 1 Tabular listing of schedule of events and assessments and procedures of the study

Study periods	Before surgery	Surgery	Discharge from hospital	90-day follow-up	12-month follow-up
Visit	1	2	3	4	5
Time (days)	0 (-7–0)	0	5 (3–14)	90 (± 10)	365 (± 30)
Patient information and informed consent	x		(x)	(x)	
Demographics	x				
Medical history	x				
Inclusion /exclusion criteria	x				
Physical examination	x		x	x	
Laboratory examinations					
Quick/INR/PTT		x			
Thrombocyte count		x			
Randomisation	x				
Other examinations (CT scan)	x		x	x	
Haematoma volume	x		x	x	
Administer medical device (burr hole covers and screws)		x			
Primary outcome					
Patient satisfaction (ANA)				x	x
Secondary outcomes					
Impairment in ADLs				x	x
Skin depression				x	x
HrQoL (EQ-5D)	x			x	x
Disability (mRS)	x		x	x	
Neurological status (NIHSS)	x		x	x	
Complications (CDG)			x	x	x
Adverse events	x	x	x	x ^B	x

ADLs, activities of daily living; ANA, Aesthetic Numeric Analogue; CDG, Clavien-Dindo Grading; EQ-5D, euroQol five dimension; HrQoL, health-related quality of life; INR, international normalised ratio; mRS, modified Rankin Scale; NIHSS, National Institute of Health Stroke Scale; PTT, partial thromboplastin time.

Patient and public involvement

Other than recruiting patients admitted to our hospital, it is not intended to involve patients and the public in the design, conduct and reporting of this research.

ETHICS AND DISSEMINATION

Despite the generally favourable risk profile and outcome of burr hole trepanation for cSDH, skin depressions may occur weeks and months after haematoma reabsorption.³⁴ These are frequently considered aesthetically unsatisfactory by patients and may lead to functional restrictions, for example, when combing, hairdressing or washing. In own clinical experience, patients reported being stared-at for these skin depressions, evoking feelings of astonishment and aversion from both family members and strangers. With an increasing number of senior citizens in good physical/mental health and leading active social lives, the aesthetic aspect of outcome gains new importance. Today's elderly patients do no longer content themselves with a basic surgical procedure, but—as informed

customers—expect optimal surgical results topped with an excellent service.⁹

In theory, burr hole covers represent an effective, easy-to-apply and relatively inexpensive solution to prevent cosmetically and functionally unfavourable skin depressions.⁴ Our survey has clearly demonstrated that—in order to improve the acceptance of this technical nuance—its efficiency needs to be demonstrated first.⁵ Moreover, as the intervention is unlikely to improve any 'hard outcome' such as disability or survival, more data should substantiate its safety.

We consider a prospective, randomised, blinded and controlled study design optimal to prove a causal relationship between the study intervention and outcome. A clear strength of this study is that patients with bilateral cSDH can be included and serve as their own internal controls. Any retrospective approach to the study question, or applying the burr hole cover in a prospective fashion and comparing it to a (historical) control group is not possible, as the outcome of interest (ANA scale) has

not been established in patients before, as well as for the likelihood of selection bias. The study aim corresponds to the value-based medicine approach of modern patient-centred medicine and results shall be published in peer-reviewed journals.

Trial status

The study has started enrolling patients on 29 January 2019.

Safety considerations

Burr hole covers are applied according to an SOP (online supplementary digital content 2) and the medical device is approved for the studied application. All device deficiencies, (severe) adverse event and (severe) adverse device effects are systematically recorded. The Clinical Trials Centre (CTC) of the University of Zurich externally monitors the trial.

Follow-Up

Participating patients are followed up to 12 months postoperative.

Unblinding

Maintenance of trial treatment randomisation codes will be done by the electronic data capturing system (run by the CTC Zurich), using a built-in tool for randomisation. Breaking codes is not allowed. Unblinding (and revealing a participant's allocated intervention) towards the patient is permissible only if the trial is suspended, prematurely terminated due to security concerns or completed.

Data managements and statistical analysis

The data are hosted by the CTC, University of Zurich. Electronic case report forms (eCRFs) are implemented. All data are stored on a server in a dedicated database. A role concept with personal passwords (site investigator, statistician, monitor, administrator, etc) regulates permission. Electronic patient data will be stored for 15 years until trial completion.

Handling of missing data

First, the risk of missing data will be minimised by regular data reviews, also with an intention to identify at risk patients for lack of follow-up data. Even though the effect of skin depression is likely more pronounced at 12 months, compared with 90 days postoperative, we intentionally chose to select the 90-day time point as primary outcome in order to minimise drop-out. Contingency plans foresee home/rehabilitation visits by study personnel to obtain otherwise missing data in patients who cannot show up for the planned 90 days or 12 months follow-up.¹⁰ Patients who die during the study interval (or cannot be evaluated as aphasic or in too poor clinical condition) and in whom for this reason the primary endpoint cannot be obtained will be recorded as not assessable for the primary outcome. Sensitivity analyses will be performed for this study.

If, despite the above-mentioned mechanisms, missing data are present, we use the following protocol: first, mechanisms of missing data are assessed. If the data are deemed missing at random, and there is <10%–15% of patients with time point missing data, then case deletion will be used (and additional patients will be recruited). Second, if the missing data mechanism is not at random, multiple imputation will be performed, a well-accepted method for intention-to-treat (ITT) analysis in randomised controlled trial with missing outcome data.^{10 11}

Determination of sample size

Based on an expected mean satisfaction score of 9/10 on the ANA in the intervention and 7/10 on the ANA in the control group, $n=37$ patients need to be randomised in each study arm in order to find a statistically significant difference in the primary outcome with alpha set at 0.05, a power of 80% and an estimated SD of 3.⁴ Based on a total sample size of $2 \times 37 = 74$, with an estimated drop-out rate of 10%, we plan to include $n=80$ patients in total.

Methods used to minimise bias

A computerised randomisation tool, provided by the electronic data capturing system, is used with the only strata being unilateral or bilateral cSDH. The random allocation sequence is generated by the CTC, University of Zurich. Study physicians conduct patient enrolment and randomisation after basic patient data have been entered into eCRFs. Due to the randomisation process, patients with unilateral cSDH are likely to be well balanced for most important parameters that could potentially influence the primary outcome. In patients with bilateral cSDH, each patient serves as his/her own control, which minimises the risk of bias (=setting similar to that of a n-of-1 clinical trial but without repetitive crossover).^{12 13}

Patients with unilateral cSDH will be randomised in a 1:1 fashion into the intervention or control group, respectively. Patients with bilateral cSDH will be randomised in a 1:1 fashion concerning the intervention side, being either the side with more or lesser haematoma size (figure 2).

Patients will be blinded for allocation to the study group/side, but surgeons will not be. Patients will not be aware of the study group/side, since the operation takes place under general anaesthesia. The fact that patients are blinded for the study group allocation will be mentioned in the discharge letter (in order to inform the family physician), and the neurosurgical team of nurses and physicians will also be informed not to 'unblind' the patient.

The primary endpoint and most of the secondary endpoints will be determined by mailed questionnaires. This way, the patient will not be influenced by the presence of the physician when judging on satisfaction with the aesthetical result of the surgery. In addition, all data are collected by a dedicated study coordinator (EJ), who is not involved in the patient care (=independent outcome assessment).

Primary analysis

The main analysis will be according to the ITT protocol. An as-treated analysis will be performed, additionally.

Satisfaction on the ANA scale for both the frontal and parietal scar are measured separately, but a mean satisfaction score is built by adding the values and dividing the sum by two. For analysis of the primary outcome, the results obtained in the intervention group (unilateral cSDH) and on the intervention side (bilateral cSDH) will be combined and compared with the combined results obtained in the control group and on the control side. As the dependent variable is a quantitative variable on an interval scale, a rank-sum test is appropriate to analyse group differences. Even though no formal minimum clinically important difference (MCID) of the ANA scale has been determined, we powered the study to detect an in-between group difference in outcome of two points, as—abstracted from the numeric rating scale for pain (also ranging between 0 and 10)—a change of two points is considered to be well above the MCID,¹⁴ therefore, resulting in a clinically meaningful improvement for the patient.

Subgroup analyses will be made for patients with bald heads versus patients with scalp hair, male versus female patients, patients <60 years versus ≥60 years and for patients with bilateral cSDH.

Secondary analyses

As the remaining secondary outcomes are not side-specific but reflect the condition of the patient as a whole, the remaining secondary analyses will compare results obtained in patients with unilateral cSDH randomised into either the intervention or control group.

As the safety outcomes are specific for the incision site and side, for the safety analyses the results obtained in the intervention group and on the intervention side will be combined and compared with the combined results obtained in the control group and on the control side.

For the outcomes that are quantitative (hrQoL on the EQ-5D) Student's t-tests or rank-sum tests will be applied, depending on normally distributed data or not. For the outcomes that are categorical (type of impairment with ADLs, disability on the mRS, neurological outcome on the NIHSS, complications on the CDG) descriptive analyses and χ^2 tests will be applied. For the outcomes that are binary (impairment with ADLs, skin depression, etc), logistic regression analysis will be performed, calculating the OR and 95% CIs.

Interim analyses

Once data of 50 patients with completed 90-day follow-up data have been collected, the primary endpoint and the safety analyses will be performed.

Quality assurance

The study is conducted in accordance with Good Clinical Practice guidelines. All source data are accessible for monitoring, audits and inspections. Authorities have

the right to perform inspections and on-site auditing. External monitoring will be performed by the CTC, University of Zurich, as detailed in a monitoring plan including prestudy, site initiation, routine monitoring and close-out visits, considering local infrastructure, completeness of documents, patient safety, adherence to the study protocol, data quality entered into the eCRFs and the trial master file.

Progress of patient inclusion and data completeness is continuously (at least once every 2 weeks) checked by a study coordinator (EJ).

Expected outcomes of the study

The study will shed more light on the question, whether patient satisfaction with the aesthetic result of the surgical procedure can be improved by adding burr hole covers on the burr holes after trepanation for cSDH. An improvement in patient satisfaction would likely be conferred through the decreased prevalence of skin depressions, as a strong difference in prevalence of skin depressions was previously found in two retrospective studies.^{3,4} The study will moreover allow to understand better, whether the application of burr hole covers increases the risks of complications, for example, cSDH recurrence or SSIs. Results of the study are likely to affect future management of cSDH patients.⁵

Duration of the project

Recruitment is expected to be completed by the end of January 2021, with final follow-up collected until January 2022. Publication of the final results is expected around 6 months after last patient out.

Project management

The principal investigators (MNS and MRG) are responsible for patient inclusion, quality of data collection and adherence to the protocol. They are supported by a team of site investigators, a dedicated study coordinator (EJ), the monitoring staff and the sponsor (LR).

All patients and/or next-of-kin will give written informed consent to contributing study physicians. Authorship for publications will be determined according to the recommendation given by the International Committee of Medical Journal Editors. No use of professional writers is planned.

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Contributors Those persons listed as authors on the manuscript have made substantial contributions to the conception or design of the work, are currently

involved in acquiring, analysing or interpreting the data for the work. They all have been active in drafting or revising the study protocol for important intellectual content, which is basis of the current article. All authors have approved the final version to be published. They agreed to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved. In detail: MNS, KA, FV, JV, EJ, PS, SV, OB, NRS, OB, LR and MRG designed the study, are local (principal) investigators or other key persons. MNS acquired the funding. MNS reviewed the literature and drafted the manuscript. KA, FV, JV, EJ, PS, SV, OB, NRS, OB, LR and MRG contributed to drafting of the manuscript. All authors read and approved the final manuscript.

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Competing interests None declared.

Patient consent for publication Not required.

Ethics approval The study protocol has been approved by the local IRB (Kantonale Ethikkommission Zürich) on 29 January 2019 (BASEC 2018–01180). Protocol modifications have to be approved by the local IRB and communicated to trial registries.

Provenance and peer review Not commissioned; externally peer reviewed.

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